IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants:	Anand R. BAICHWAL, et al.
Serial Number:	10/047,060
Filed:	January 14, 2002
Entitled:	**CONTROLLED RELEASE INSUFFLATION CARRIER FOR MEDICAMENTS**
Examiner:	Carlos A. AZPURU (Art Unit: 1615)

CERTIFICATION UNDER 37 C.F.R. § 1.10

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APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. § 1.193

Sir:

Appellants submit this Reply Brief in response to the Examiner's Answer mailed on February 20, 2004. An original and two copies of this Brief are submitted herewith. The following remarks are responsive to the Examiner's Answer.

I. GROUPING OF CLAIMS

Claims 26-43 are pending in the application. The Examiner asserts that claims 26-43 stand or fall together. Appellants maintain that Group I, claims 26-42, and Group II, claim 43, are separately patentable for purposes of the rejection under 35 U.S.C. § 112, second paragraph. The claims of each group stand or fall together.

II. ARGUMENTS

A. Summary

Appellants claim a device for delivering to a patient a cohesive composite of a medicament and a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum of a specified particle size. Appellants' claims 26-43 stand rejected under 35 U.S.C. § 112, second paragraph, and 35 U.S.C. § 102(b).

Both of the outstanding rejections stem from the Examiner's persistent and unfounded refusal to recognize that the claimed invention is not limited to the delivery device alone, but rather also includes the novel pharmaceutical composition contained in and delivered by the device. More specifically, the rejection under § 112, second paragraph, is based on an unsupported objection to Appellants' defining their claimed invention using a combination of device and composition limitations. The rejection under § 102(b) is based on the incorrect premise that references teaching the device limitations but otherwise silent with respect to the composition limitations of the claimed invention can anticipate Appellants' claims. Appellants respectfully submit that these rejections are clearly improper and should be reversed.

B. Rejection of Claims 26-43 under 35 U.S.C. § 112, second paragraph

The Examiner asserts that claims 26-43 are indefinite because they lack device limitations that particularly point out the claimed invention, and attempt to use composition limitations to define the claimed device. Notably, the Examiner does not assert that Appellants' claims are unclear, but rather objects to Appellants' use of composition limitations to define the claimed invention. *See, e.g.,* Examiner's Answer, page 3, lines 13-19. Without authority, the Examiner simply refuses to recognize that Appellants are free to define their own invention in the desired manner, and that a patentable invention can be clearly defined using a combination of composition and device limitations.

The rejection under § 112, second paragraph, appears to be based on the following flawed analysis: (i) because Appellants' claims recite a medicament delivery device, the claimed invention can only be defined by limitations that describe the device itself, and (ii) the segregated device limitations of Appellants' claims are too broad to clearly define a patentable invention.[1]

[1] *See, e.g.,* Examiner's Answer, page 5, lines 6-9, framing the inquiry under § 112, second paragraph, as "whether the empty device would adequately define over the prior art," and answering this question "no, and the use of the pharmaceutical within the device can not make the device claims definite" (emphasis added).

This analysis, based on mischaracterization of the claimed invention and objection to alleged overbreadth, does not provide a proper foundation for an indefiniteness rejection under § 112, second paragraph. The claims are not indefinite simply because the Examiner disapproves of Appellants' decision to define their invention as the combination of a device and a composition contained within it.

The Examiner improperly attempts to analogize the composition limitations of Appellants' claims to "intended use" language in composition claims. *See* Examiner's Answer, page 3, lines 17-19. The principle that a new intended use does not confer novelty on an old composition simply is not relevant to the patentability of Appellants' claims. Appellants are not asserting novelty based on an abstract use that has no impact on the nature of the claimed product itself. Rather, Appellants' claims include specific physical limitations regarding the novel composition that is necessarily contained in and forms an integral part of the claimed medicament delivery device. The Examiner has not cited any authority suggesting that it is improper for Appellants to define their invention as a combination of a device and a novel composition within the device. A vague analogy to an inapposite principle regarding "intended use" language is not sufficient to legitimize the indefiniteness rejection.

Appellants believe that the claims of Group I, claims 26-42, are separately patentable from Group II, claim 43, for purposes of the indefiniteness rejection under § 112, second paragraph, because the claims of Group I recite the claimed device limitations, while claim 43 uses "means for" language to invoke interpretation under § 112, sixth paragraph.

1. Group I

Claims 26-42 are definite because they particularly point out and distinctly claim what Appellants regard as the invention. Specifically, the claims clearly describe novel cohesive composite particles that are contained in a delivery device having an output port, a chamber, and an actuator. As noted above, the Examiner has agreed that these claims are not unclear, and simply disagrees with Appellants' decision to define the claimed invention using a combination of composition and device limitations. Because this is not a proper basis for an indefiniteness rejection, Appellants respectfully request that the rejection of claims 26-42 under 35 U.S.C. § 112, second paragraph, be reversed.

2. Group II

Claim 43 is definite because it particularly points out and distinctly claims what Appellants regard as the invention, namely, a medicament delivery device containing a novel cohesive composite, and a mechanism for delivering the composite. Claim 43 clearly describes the novel composite, and properly invokes interpretation under 35 U.S.C. § 112, sixth paragraph, by defining the claimed delivery mechanism as a "means for delivering the cohesive composite to a nasal or oral orifice." Because claim 43 properly defines the delivery mechanism as a "means ... for performing a specified function without the recital of structure, material, or acts in support thereof," the "means for delivering ..." limitation will be interpreted by reference to "the corresponding structure, material, or acts described in the specification and equivalents thereof," according to § 112, sixth paragraph. Appellants' specification, in turn, provides the requisite "corresponding structure, material, or acts" by describing in detail a number of devices, including commercially available inhalers, that are suitable for performing the claimed delivery function.

Thus, claim 43 is definite because it clearly defines Appellants' invention in accordance with the statutorily authorized format of § 112, sixth paragraph. As noted above, the Examiner apparently finds the claims indefinite because Appellants have chosen to define their invention using a combination of composition and device limitations. Because this is not a proper basis for an indefiniteness rejection, Appellants respectfully request that the rejection of claim 43 under § 112, second paragraph, be reversed.

C. Rejection Under 35 U.S.C. § 102(b)

The Examiner maintains that claims 26-43 are anticipated by Evans, et al., U.S. Patent No. 5,239,993 and Burns et al., U.S. Patent No. 5,284,133, arguing that each of these references teaches a medicament delivery device having an output port, a chamber, and an actuator as claimed. The Examiner has not asserted that either reference teaches the composition limitations of Appellants' claims, and instead improperly insists that composition limitations cannot be used to define the claimed device over the prior art. The Examiner has not cited any legal authority for this position, and has not adequately addressed Appellants' citations of authority to the contrary.

A proper anticipation rejection requires that each and every limitation of a claim be found in a prior art reference. *See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 58

U.S.P.Q.2d 1508, 1512 (Fed. Cir. 2001). Accordingly, claims 26-43 cannot be anticipated by the cited references, which do not teach, and have never been asserted to teach, a cohesive composite of a medicament and a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum of a specified particle size as claimed. The Examiner asserts that "the composition limitations were considered, however they did not define over the prior art references which meet all the device limitations of the instant claims." *See* Examiner's Answer, page 4, lines 2-3.[2] This argument is simply nonsensical. The composition limitations must be considered as part of the claimed invention as a whole, and cannot be blindly ignored in making a prior art rejection. In this instance, a novelty-defeating piece of prior art must teach both the composition limitations and the device limitations to anticipate the claims.

The case law establishes that a single novel feature added to a known combination is patentable, and that novelty can be conferred on a prior art device by a claim element that is not part of the device itself. For example, in *In re Bernhart*, the Court of Customs and Patent Appeals held that a prior art machine that performs a new algorithm is patentable even though "... the only apparatus recited is the admittedly old computer and plotting machine and the sole distinction presented therein upon which patentability could be predicted is ... the algorithm which the computer is to solve." *In re Bernhart*, 417 F.2d. 1395, 1398 (C.C.P.A. 1969) (emphasis added). Similarly, numerous U.S. patents have issued with claims reciting a prior art device containing a novel composition. For example, U.S. Patent Nos. 5,597,582 and 6,030,642 each claim a novel pharmaceutical formulation contained in a prior art gelatin capsule. The issuance of such claims demonstrates that a known device or carrier can be made novel by the inclusion of a stored formulation. Thus, the case law and issued patents demonstrate that Appellants' claims are novel because they include novel composition limitations, even if those limitations do not represent an improvement to the device itself.

The Examiner has acknowledged that Appellants' composition is novel. *See* Final Office Action of February 26, 2003, page 8, lines 3-4. Therefore, claims 26-43 reciting a delivery device containing the novel composition simply cannot be anticipated by the cited art. As explained by the Court of Customs and Patent Appeals in *In re Bernhart*, "[i]f the prior art does not show or suggest the improved element itself, it defies logical reasoning to say that the same

[2] *See also* Examiner's Answer, page 5, line 17 – page 6, line 4, suggesting that the pharmaceutical composition limitations of Appellants' claims should be disregarded in the anticipation analysis because they describe "an unclaimed invention within the device."

prior art suggests the use of that improved element in a combination." *In re Bernhart*, 417 F.2d. 1395 at 1402 (emphasis added). Accordingly, Appellants respectfully submit that the rejection of claims 26-43 under 35 U.S.C. § 102(b) is improper and should be reversed.

III. CONCLUSION

For the reasons advanced above, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the outstanding rejections, remand the application to the Examiner, and direct the Examiner to issue a Notice of Allowance.

Appellants note that this Reply Brief is timely filed within two months of the mailing date of the Examiner's Answer. In a telephone conversation with the undersigned on March 11, 2004, Examiner Azpuru confirmed that February 20, 2004, the mailing date stamped on the first (title) page of the Examiner's Answer, is the correct mailing date as entered in the Patent and Trademark Office PAIR system database.

No fees are believed to be due in connection with the filing of this Reply Brief. However, please charge any payments due or credit any overpayments to our Deposit Account No. 08-0219.

Respectfully Submitted,

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